REMARKS

In view of the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow Claims 1-16, the only claims pending and currently under examination in this application.

The Specification has been amended to update the status of the parent applicaiton, as requested.

The claims have been amended to include correlating the effect of assayed compound compositions on the non-mammalian test organisms to mammalian organisms. Support for this amendment is found in the specification at pages 14 and 15.

As no new matter has been added by way of this amendment, the Applicants respectfully request the entry thereof.

Claims 1-16 were rejected under the judicially created doctrine of obviousness type double patenting over Claims 1-15 of U.S. Patent No. 6,365,129. In view of the enclosed Terminal Disclaimer, this rejection may be withdrawn.

Objections to the Specification

The Specification has been amended to update the status of the parent application. Accordingly, the objection to the specification may be withdrawn.

35 U.S.C. § 102 rejection of claims 1-7, 10-13, and 16

Claims 1-7, 10-13 and 16 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Wasserkort.

The present claims are directed to methods of performing high-throughput toxicity screens on non-mammalian multi-cellular organisms in order to estimate toxicity on

mammalian organisms. A feature of the claimed methods is that they include a step of using the determined effect of the test agent to estimate the effect the agent will have on a mammalian organism. The claimed methods find use, among other applications, in screening large libraries of compounds and compound combinations for potential toxicity to mammalian organisms, where the claimed methods can be performed more rapidly and more cost-effectively than assays performed directly on mammalian organisms. Example II in the specification (pages 14-15) shows that in the compounds tested, there is a 90% toxic assessment correspondence between flies and mice and rats.

In contrast to the claimed methods, Wasserkort fails to teach a step of using results in insects to estimate results in mammalian organisms. Specifically, no direct comparative experiment was done between adult flies and higher mammalian species in Wasserkort. Therefore, the methods disclosed in Wasserkort do not teach at least this estimating element of the present claims.

In addition, Claims 12, 13 and 16 are further distinguished from Wasserkort in that these claims are directed to a method of screening for candidate compounds with anti-toxin activity. As stated in the claims, the candidate antitoxin compound is contacted with a population of non-mammalian organisms that also are contacted with the toxin. A reduction in observed toxicity indicates that the candidate compound has anti-toxin activity. Nothing in Wasserkort teaches such an assay, as Wasserkort says nothing about testing for antitoxin activity of candidate compounds.

Therefore, it is respectfully submitted that Wasserkort does not anticipate Claims 1-7, 10-13 and 16 and that the rejection of these claims under 35 U.S.C. § 102(b) may be withdrawn.

Claims 1-7, 10-13 and 16 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Lynch. The assay disclosed in Lynch is not a toxicity assay but instead is a teratogenicity assay. Lynch states that the purpose of the work was to "create a new, rapid and economical bioassay useful in screening for potential developmental toxicants." Lynch also

teaches that the pregnant females are the animals exposed to the toxins and the effect of this parental exposure on the phenotypes of the offspring is that which is evaluated. This description of the assay methods is in complete agreement with the accepted definition of teratogenicity tests. Enclosed with this response please find an excerpt from Fundamental Toxicology for Chemists, which excerpt provides definitions for both teratogenicity and toxicity.

In contrast, a toxicity test is one that looks at the effect of a compound on the immediate organism to which it is exposed, and not the offspring of the exposed organism. The methods described in the present claims must be classified as toxicity screens as they specifically assess the effect of candidate compounds on the exposed animal and not on their offspring.

In addition, Claims 12, 13 and 16 are further distinguished from Lynch in that these claims are directed to a method of screening for a candidate compound's antitoxin activity, where the candidate compound and a known toxin are both contacted with the organism. Nothing in Lynch teaches or suggests such an assay, as Lynch says nothing about testing antitoxin activity of candidate compounds.

Because the present claims are directed to methods of performing a toxicity assay, or an anti-toxin assay, and not to methods of performing a teratogenicity assay, Lynch fails to anticipate the claimed methods. Therefore, the rejection of Claims 1-7, 10-13 and 16 under 35 U.S.C. § 102(b) over Lynch may be withdrawn.

35 U.S.C. § 103 rejection of claims 8-9 and 14-15

Claims 8-9 and 14-15 have been rejected under 35 U.S.C. § 103(a) as obvious over either Wasserkort or Lynch for the reason that the only difference between the claims and the cited references is the number of compounds tested, which is asserted to be an obvious difference.

As pointed out above, Wasserkort does not provide a method for estimating toxicity in mammalian animals using non-mammalian organisms as described in the present claims.

There is no experimental data in Wasserkort that directly compares the toxicity of compound compositions on both non-mammalian and mammalian animals. Also from the arguments above, Lynch describes a teratogenicity screen, not a toxicity screen. As such, both Lynch and Wasserkort fail to teach or suggest the elements of the present claims and this rejection may be withdrawn.

Rejection of Claims 1-16 Under the Judicially Created Doctrine of Obviousness Type Double Patenting

Finally, Claims 1-16 have been rejected under the judicially created doctrine of obviousness type double patenting ovre Claim 1-16 of United States Patent No. 6,365,129. In view of the enclosed terminal disclaimer, this rejection may be withdrawn.

Conclusion

In view of the above amendments and remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issuance.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: 6·22·04

By: _____
Bret E. Field
Registration No. 37,620

- Excerpt from Fundamental Toxicology for Chemists
- Terminal Disclaimer over United States Patent No. 6,365,129

BOZICEVIC, FIELD & FRANCIS LLP
200 Middlefield Road, Suite 200
Menlo Park, CA 94025
Telephone: (650) 327-3400
Facsimile: (650) 327-3231

F:\DOCUMENT\tosk\004CON\response to 3-22-04 office action.doc